GlaxoSmithKline

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Dockets Management Branch (HFA-305),
Food and Drug Administration,
5630 Fishers Lane (Room. 1061),
Rockville, MD 20852.
USA

Harmire Road
Barnard Castle
County Durham
DL12 8DT

Tel. +44 (0)1833 690600
Fax. +44 (0)1833 692300
www.gsk.com

12th May 2004

RE: "Electronic Records; Electronic Signatures; Public Meeting" Docket No. 2004N-0133.

Dear Sir/Madam:

GlaxoSmithKline a research-based pharmaceutical company is engaged in the discovery, development, manufacture, and sale of pharmaceutical products. We welcome the opportunity to submit a request to speak at the FDA Public Meeting on Part 11 on 11th June 2004 and submit the following presentation abstract. The abstract responds to the question *'What potential changes to Part 11 would encourage innovation and technical advances consistent with the agency's need to safeguard public health?'* posed in the Agency's notice for the public meeting published 8th April 2004. Thank you for your consideration.

Yours Sincerely,

Dr Guy Wingate
Director, Global Computer Validation
Global Manufacturing & Supply
GlaxoSmithKline

Tel: +44-1833-692848
E-mail: guy.wingate@gsk.com

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Part 11 in Support of Innovation & New Technology

(Presenter: Dr Guy Wingate, Director – Global Computer Validation, Global Manufacturing & Supply, GlaxoSmithKline Harmire Road, Barnard Castle, County Durham, DL12 8DT, England)

GlaxoSmithKline is a research-based pharmaceutical company is engaged in the discovery, development, manufacture, and sale of pharmaceutical products. Our proposed presentation supports the FDA's recent thinking on Part 11 embodied in the FDA's *Final Guidance on Scope and Application of Part 11* issued September 2003. It will set out how this thinking will help foster innovation and new technology to support better understanding and control of our manufacturing processes (e.g. Process Analytical Technology). The presentation will highlight the role of:

- Preserving the narrow scope of Part 11 through emphasizing the role of predicate rules and focusing on required records and signatures, not systems or data
- Allowing all record controls to be risk based (not just audit trail, validation, record retention, and copying).

The consequences of applying these criteria to new and novel computerized applications will be explored. Establishing a common understanding of expectations is key to supporting investment. Specific topics to be raised will include:

- Distinguishing required records in predicate rules from interim data
- Understanding the role of supporting computerized systems and the potential exclusion of Programmable Logic Controllers and real-time process analytical instrumentation from the scope of Part 11
- Applying design for impact principles to establish appropriate record controls
- Setting limits on expectations for reprocessing records
- Validating record and signature controls in context of expectation for overall system validation
- Potential exclusion of computerized systems and associated instrumentation used to generate "data" for enhancing "process understanding" under the PAT initiative

The presentation will conclude with a summary of benefits of adopting a risk-based approach to Part 11 in support of innovation and new technology. GlaxoSmithKline recommend that FDA revise the Part 11 Rule to align it with associated Final Guidance already issued so that FDA-regulated industries have an up to date set of requirements consolidated in law.